

Please type a plus sign (+) inside this box.

Approved for use through 4/30/2003. OMR 0651-003!  
SUBSTITUTE for PTO/SB 08A (05-03), Information Disclosure Statement by Applicant  
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE

**STATEMENT BY APPLICANT**

(use <sup>U</sup>as many sheets as necessary)

1

of

3

**COMPLETE IF KNOWN**

<b>Application Number</b>	<b>09/831,182</b>
---------------------------	-------------------

July 18, 2001

<b>First Named Inventor</b>	Colloca, Stefano
-----------------------------	------------------

1648

Examiner Name	Winkler, U.
---------------	-------------

Attorney Docket Number	ITR0056P
------------------------	----------

## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

[illegible]

**Examiner  
Signature**

Date Considered

9/27/04

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SEND TO: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

Computer generated form "IDS Form" (IDS Folder), Merck & Co., Inc., 06/27/2003

Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE

## STATEMENT BY APPLICANT

(use as many sheets as necessary)

2

of

3

COMPLETE IF KNOWN	
Application Number	09/831,182
Filing Date	July 18, 2001
First Named Inventor	Colloca, Stefano
Group Art Unit	1648
Examiner Name	Winkler, U.
Attorney Docket Number	ITR0056P

## OTHER NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
W		Baron, U. et al. "Co-regulation of two gene activities by tetracycline via a bidirectional promoter", Nucleic Acids Research, 1995, Vol. 23, pp. 3605-3606
		Brough, D. et al. "A Gene Transfer Vector-Cell Line System for Complete Functional Complementation of Adenovirus Early Regions E1 and E4", Journal of Virology, 1996, Vol. 70, pp. 6497-6501
		Bett, A. et al. "An efficient and flexible system for construction of adenovirus vectors with insertions or deletions in early regions 1 and 3", Proc. Natl. Acad. Sci. USA, 1994, Vol. 91, pp. 8802-8806
		Calos, M. "The potential of extrachromosomal replicating vectors for gene therapy", TIG, 1996, Vol. 12, pp. 463-466
		Calos, M. "Stability without a centromere", Proc. Natl. Acad. Sci. USA, 1998, Vol. 95, pp. 4084-4085
		Deuschle, U. et al. "Tetracycline-Reversible Silencing of Eukaryotic Promoters", Molecular and Cellular Biology, 1995, Vol. 15, pp. 1907-1914
		Engelhardt, J. et al. "Ablation of E2A in recombinant adenoviruses improves transgene persistence and decreases inflammatory response in mouse liver", Proc. Natl. Acad. Sci. USA, 1994, Vol. 91, pp. 6196-6200
		Freundlieb, S. et al. "A Tetracycline Controlled Activation/Repression System with Increased Potential for Gene Transfer into Mammalian Cells", The Journal of Gene Medicine, 1999, Vol. 1, pp. 4-12
		Gossen, M. et al. "Transcriptional Activation by Tetracyclines in Mammalian Cells", Science, 1995, Vol. 268, pp. 1766-1769
		Hitt, M. et al. "Techniques for Human Adenovirus Vector Construction and Characterization", Methods in Molecular Genetics, 1995, Vol. 7, pp. 13-30
		Hitt, M. et al. "Human Adenovirus Vectors for Gene Transfer into Mammalian Cells", Advances in Pharmacology, 1997, Vol. 40, pp. 137-206
		Kozarsky, K. et al. "In Vivo Correction of Low Density Lipoprotein Receptor Deficiency in the Wantanabe Heritable Hyperlipidemic Rabbit with Recombinant Adenoviruses", The Journal of Biological Chemistry, 1994, Vol. 269, pp. 13695-13702
		Krougliak, V. et al. "Development of Cell Lines Capable of Complementing E1, E4, and Protein IX Defective Adenovirus Type 5 Mutants", Human Gene Therapy, 1995, Vol. 6, pp. 1575-1586
		No, D. et al. "Ecdysone-inducible gene expression in mammalian cells and transgenic mice", Proc. Natl. Acad. Sci. USA, 1996, Vol. 93, pp. 3346-3351
		Parks, R. et al. "A helper-dependent adenovirus vector system: Removal of helper virus by Cre-mediated excision of the viral packaging signal", Proc. Natl. Acad. Sci. USA, 1996, Vol. 93, pp. 13565-13570

Examiner Signature

Date Considered

4/27/04

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SEND TO: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

Please type a plus sign (+) inside this box.

Approved for use through 4/30/2003. OMB 0651-0031  
SUBSTITUTE for PTO/SR/08 (OS-03), Information Disclosure Statement by Applicant  
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO		<b>COMPLETE IF KNOWN</b>	
<b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b> (use as many sheets as necessary)		Application Number	09/831,182
		Filing Date	July 18, 2001
		First Named Inventor	Colloca, Stefano
		Group Art Unit	1648
		Examiner Name	Winkler, U.
		Attorney Docket Number	ITR0056P
Sheet 3 of 3			

DIPT  
JUL 14 2003  
JUL 17 2003  
TECH CENTER 1600/2900

RECEIVED  
JUL 17 2003  
TECH CENTER 1600/2900

OTHER NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
W		Spencer, D. et al. "Controlling Signal Transduction with Synthetic Ligands", Science, 1993, Vol. 262, pp. 1019-1024
		Wang, Y. et al. "A regulatory system for use in gene transfer", Proc. Natl. Acad. Sci. USA, 1994, Vol. 91, pp. 8180-8184
		Yang, Y. et al. "Cellular immunity to viral antigens limits E1-deleted adenoviruses for gene therapy", Proc. Natl. Acad. Sci. USA, 1994, Vol. 91, pp. 4407-4411
		Amalfitano, A. et al. "Production and Characterization of Improved Adenovirus Vectors with the E1, E2b, and E3 Genes Deleted", Journal of Virology, 1998, Vol. 72, pp. 926-933
		Dedieu, J. et al. "Long-Term Gene Delivery into the Livers of Immunocompetent Mice with E1/E4-Defective Adenoviruses", Journal of Virology, 1997, Vol. 71, pp. 4626-4637
		Gorziglia, M. et al. "Elimination of both E1 and E2a from Adenovirus Vectors Further Improves Prospects for In Vivo Human Gene Therapy", Journal of Virology, 1996, Vol. 70, pp. 4173-4178
		Gao, G. et al. "Biology of Adenovirus Vectors with E1 and E4 Deletions for Liver-Directed Gene Therapy", Journal of Virology, 1996, Vol. 70, pp. 8934-8943
		Recchia, A. et al. "Site-specific integration mediated by a hybrid adenovirus/adeno-associated virus vector", Proc. Natl. Acad. Sci. USA, 1999, Vol. 96, pp. 2615-2620
		Rittner, K. et al. "Conditional Repression of the E2 Transcription Unit in E1-E3-Deleted Adenovirus Vectors is Correlated with a Strong Reduction in Viral DNA Replication and Late Gene Expression In Vitro", Journal of Virology, 1997, Vol. 71, pp. 3307-3311
		Zhang, Y et al. "A new logic for DNA engineering using recombination in <i>Escherichia coli</i> ", Nature Genetics, 1998, Vol. 20, pp. 123-128

RECEIVED  
SEP 1 2003  
TECH CENTER 1600/2900

Examiner Signature	<i>[Signature]</i>	Date Considered	4/27/04
--------------------	--------------------	-----------------	---------

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SEND TO: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.